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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,308	07/29/2003	Julie Hazel Campbell	229752001220	4466

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EXAMINER	
ISABELLA, DAVID J	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/628,308	CAMPBELL ET AL.	
	Examiner	Art Unit	
	DAVID J. ISABELLA	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 3/3/06
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Status of the Claims

As per applicant's amendment filed on 6/16/2006, all previous pending claims have been cancelled and claims 35-56 have been newly added. The previous claims were directed to isolated tissue graft and a method for making a tissue graft and no restriction was effected by the previous examiner. However, applicant's current claims are directed solely to the method for making a tissue graft and therefor the office will consider this amendment as provisionally elected the invention directed to the method and not the tissue graft. Therefor any further amendments to the claims that may contain subject matter directed to the tissue graft will be withdrawn from further consideration as being directed to a non-elected invention.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 35-56 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over any of Brauker et al [5741330], Moukheibir (USPN 4,490,137, as cited in applicant's IDS) and Gosserez [4902294].

Brauker et al discloses that typical catheter left in the body, including the peritoneal cavity will have non-vascularized collagenous material formed thereon.

> In typical catheter designs, a thick foreign body of non-vascularized collagenous material is produced around the catheter that acts as a conduit for bacteria. In the present invention, vascularization around the catheter prevents tunnel site infections because necrosis of the tissue is prevented and the vascular bed bathes the area with the entire repertoire of blood borne immune cells. In another embodiment, a flange on a catheter would be covered with a vascularizing material, or would be made entirely from the material.

Gosserez discloses that silicone implants placed in the body's cavity creates the formation of myofibroblasts that completely surrounds the implant.

> Nevertheless, whichever category of prosthesis is used, its implantation leads to a foreign body reaction in the organism, this reaction manifesting itself in the formation of a living membrane made up of, among other things, fibroblast collagen and myofibroblasts which completely surround the prosthesis and isolate it from the organism.

The method for placing traditional (ie. non-Brauker et al type) catheters (Tenckhoff) and the prosthesis and leaving it in the peritoneal and body cavity, respectively, would provide the method steps as set forth in newly added independent claim 35 as reproduced below.

> 35. (New) A method of producing a tissue, comprising placing a molding support within a body cavity for a time and under conditions sufficient for non-vascularized tissue comprising myofibroblasts to form on the molding support.

Claim 36, as broadly worded reads on the removal of each of the peritoneal catheter and the mammary prosthesis from the patient.

Claim 37 as the catheter and the prosthesis is removed from the cavity, some of the tissues that formed on the devices would, inherently become separated from the device upon removal from the patient.

Claim 39, each of the catheter and mammary prosthesis is placed in the cavity by surgical implantation.

Claim 40, the peritoneal catheter would have mesothelial cells attachment as claimed.

Claims 42-44, see materials and shape of the device as disclosed by Brauker et al or Moukheibir.

Claims 45-48, the tissue formed on the device would be tubular in form and could be used in the manner as set forth in claims 45-48.

Claims 50-52, the tissue is autologous and the peritoneal catheter is placed in a human recipient.

Claims 54-56, see catheter of Moukheibir.

Moukheibir discloses a peritoneal dialysis catheter that inherently meets the method steps and contains each element as claimed. See column 1, lines 13-20 for a Tenckhoff peritoneal dialysis catheter, which is disclosed in [0038] and [0066] of the specification as being a suitable prosthetic device. Therefore, the prosthetic device has an elongated outer tubular member with perforations (18), inner elongated member and external portion. The inner elongated member comprises a tube around which vascular or non-vascular tissue would be capable of growing.

Double Patenting

20. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 35-56 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,626,823. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent includes every limitation of the claims of the application. The newly added claims are broader in scope than the patented claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 571-272-4749. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DAVID J ISABELLA
Primary Examiner
Art Unit 3738

DJI
9/12/2006